remission. Significant predictors of medical costs ($p<0.05$) were disease activity, disease history for both groups, age and employment status for CD subjects and previous colectomy for UC subjects. **CONCLUSIONS:** Our analyses show that medical costs of patients with IBD can in part be predicted. However, predictors differ between CD and UC patients: Disease activity and disease history are the most important cost predictors, while age and employment status are only important cost predictors for CD patients.

Individual's Health – Clinical Outcomes Studies

PIH1

COMPARISON OF UNINTENDED PREGNANCY RATES IN USERS OF 84/7, 21/7, AND 24/4 ORAL CONTRACEPTIVE REGIMENS

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OBJECTIVES: To compare pregnancy rates post initiation on oral contraceptive (OC) users of 84 days levonorgestrel/ethinyl estradiol (EE) 0.15mg/0.03mg tablets plus EE 0.01mg for 7 days in place of placebo (84/7) or, 21 days combined EE/progestin plus 7 days placebo (21/7) or 24 days EE/progestin plus 4 days placebo (24/4) over the course of 1 year. **METHODS:** Data for this study were obtained from the US i3 Invision™ Data Mart and spanned the period from January 1, 2006 through March 31, 2010. Patients were included if they received the medication of interest (with first such receipt identified as index date), were age 15-40 on index date, and had continuous insurance coverage from index date through 1 year post index date. Two distinct analyses were performed: 1 comparing pregnancy rates post initiation on an 84/7 or 21/7 OC and the other comparing pregnancy post initiation on an 84/7 or 24/4 OC. The 84/7 cohort was matched to each of the alternative cohorts of interest based upon age, sex, region, business type of insurance, insurance product, and year of index date. **RESULTS:** There were 5,821 individuals in the 84/7 cohort, 650,816 individuals in the 21/7 cohort, and 111,540 individuals in the 24/4 cohort. Matching of the 84/7 cohort to each of the alternative cohorts resulted in a successful match rate of over 99% when comparing 84/7 to 21/7 or comparing 84/7 to 24/4. Pregnancy rates in the 1 year post initiation on an OC were found to be statistically significantly lower for initiators of 84/7 compared to 21/7 (3.04% vs. 5.12%; $P<0.0001$) as well as when comparing 84/7 to 24/4 (3.03% vs. 5.28%; $P<0.0001$). **CONCLUSIONS:** In this study, pregnancy rates were significantly lower in women using an 84/7 OC regimen compared to 21/7 or 24/4 regimens.

PIH2

CARESS: THE CANADIAN REGISTRY OF SYNAGIS (2005-2010)

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OBJECTIVES: To evaluate the current management of children at high-risk of RSV infection who received palivizumab prophylaxis and were enrolled in the Canadian Registry Database. **METHODS:** A prospective, observational, registry of infants who received at least 1 dose of palivizumab during the 2005-2010 RSV seasons across 29 sites. Neonatal and demographic data were collected from the parent/caregiver at enrollment. Data on palivizumab utilization, compliance, and outcomes related to respiratory illness (RI) events were collected monthly. **RESULTS:** A total of 7699 infants were enrolled with an average age of 5.4±6.0 months. Participants were typically male (56.2%), Caucasian (71.5%) with an average gestational age (GA) of 32.2±6.0 completed weeks. A total of 5237 (68.0%) infants received palivizumab for prematurity (≤35 completed weeks GA without underlying medical disorders), 646 (8.4%) had chronic lung disease, 766 (9.9%) hemodynamically significant congenital heart disease and 1050 (13.6%) were prophylaxed for other conditions such as CNS disorders, airway anomalies and cystic fibrosis. Patients received an average of 3.9±1.6 injections and 30,040 doses overall; 5.5% of patients withdrew from the study. No direct, drug related serious adverse events were identified. 460 infants had a total of 541 RI hospitalizations resulting in a hospitalization rate of 6.0%.The overall RSV positive hospitalization (RSVH) rate was 1.47%. Living with siblings ($p=0.046$) and having >5 individuals in the household ($p=0.007$) was significantly associated with time to a patient's first RSVH. Other risk factors traditionally associated with a higher risk for RSV infection, such as gender ($p=0.429$), smoking ($p=0.182$), daycare attendance ($p=0.079$), age ($p=0.213$), and compliance with treatment ($p=0.695$) were not found to be significantly correlated. **CONCLUSIONS:** The RSVH observed from 2005-2010 was 1.4% overall (range 0.3% - 2.1%) and compares favorably with international registry data despite the steady increase in the number of Canadian immunized infants with serious underlying medical disorders.

PIH3

RESPIRATORY SYNCYTIAL VIRUS HOSPITALIZATIONS IN THE CANADIAN REGISTRY FOR SYNAGIS (CARESS)

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OBJECTIVES: Paediatric advisory committee guidelines recommend palivizumab prophylaxis for specific sub-populations of infants at high risk for respiratory syncytial virus (RSV) infection. However, effectiveness of palivizumab may vary across indications and countries. The objective of our study was to determine hospitalization rates for respiratory illness (RIH) and RSV-positive infections (RSVH) following prophylaxis and compare rates found in this study with other world-wide data from published registries. **METHODS:** Neonatal and demographic data were collected prospectively across 29 national sites as part of an established CAnadian REgistry for SynagiS (CARESS) database from infants who received ≥1 dose of palivizumab during the 2005-2010 RSV seasons. Respiratory illness (RI) events were documented monthly. **RESULTS:** The 7699 infants enrolled were premature (≤35 completed weeks gestational age, without any underlying medical illnesses; n=5237), had chronic lung disease/bronchopulmonary dysplasia (n=646), hemodynamically significant congenital heart disease (n=766), or had other pre-existing conditions such as neuromuscular impairments, Down syndrome, pulmonary or airway malformations, immunocompromise or cystic fibrosis (n=1050). The overall RIH rate was 6.0%. Premature infants had a significantly lower rate (4.1%) than the other groups (range 8.7% -11.5%; B=-0.912, df=1, $p<0.005$). The overall RSVH rate was 1.47% with significant differences between groups (range 1.22% - 2.46%; $\chi2=22.606$, df=3, $p<0.0005$). Apart from hospital length of stay, morbidities differed significantly across the sub-groups during RSVH including number of ICU admissions and length of stay, number ventilated and duration of intubation, number requiring respiratory support and duration (all $p<0.05$). **CONCLUSIONS:** Hospitalization rates for RI events and RSV illness were different across the groups. Comparisons with other registries indicate that RSVH rates are in the lower range overall (range 1.3 -8.1%); however, comparisons are difficult to establish as most studies do not account for the varying lengths of observation that arise because infants are enrolled at different times during the RSV season.

PIH4

A COMPARATIVE STUDY OF RESPIRATORY SYNCYTIAL VIRUS (RSV) PROPHYLAXIS IN PREMATURE INFANTS

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OBJECTIVES: Infants 33-35 completed weeks' gestational age (GA) and those ≤ 32 weeks GA incur similar rates of respiratory syncytial virus hospitalization (RSVH) and morbidities which targets them as risk groups for RSV prophylaxis in current international pediatric advisory statements. We examined immunization regimens, compliance and outcomes of premature infants who received palivizumab within the Canadian Registry Database (CARESS). **METHODS:** Neonatal and demographic data were collected from infants receiving ≥1 dose of palivizumab during the 2006-2010 RSV seasons across 29 recruitment sites. Respiratory illness (RI) events were captured monthly. Premature infants' ≤32 weeks GA without pre-existing medical disorders (Group 1) was compared to a similar moderate-high risk group 33-35 completed weeks GA (Group 2) who received prophylaxis. **RESULTS:** 4819 patients were analyzed (Group 1, n=3746; Group 2, n=1073). Mean GA: 30.0± 3.1 versus 34.2±2.0. The groups were similar for proportion of Caucasians, mothers' who smoked daily and during pregnancy, history of atopy and number of multiples in the family. There were significant differences (Group 1, Group 2; $p<0.005$) in: mean birth weight (g) (1445±606 versus 2142±521), proportion of males (54.3% versus 63.1%), and number with siblings (54.2% versus 74.6%), siblings in daycare (13.9% versus 35.0%), ≥2 household smokers (9.9% versus 14.0%) and ≥ 5 individuals living in the household (22.7% versus 44.0%). Group 1 had significantly more complicated neonatal courses. Overall infants received 91.9%±30.7% of expected number of injections. Group 1 received more injections (3.9±1.7 versus 3.5±1.6; $p<0.005$) and had higher compliance rates (92.8% versus 88.9%; $p<0.005$). Respective RI and RSVH rates (4.5% versus 3.4%; hazard ratio=0.852, $p=0.385$) and (1.30% versus 1.3%; hazard ratio=1.233, $p=0.543$) were similar. **CONCLUSIONS:** Overall compliance with RSV prophylaxis in the premature population is high and despite the higher number of palivizumab doses in infants ≤32 weeks GA, group RI and RSVH rates were similar.

PIH5

RESPIRATORY SYNCYTIAL VIRUS (RSV) PROPHYLAXIS IN SPECIAL POPULATIONS

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OBJECTIVES: To compare palivizumab utilization and compliance in infants who meet standard indications for RSV prophylaxis versus those with pre-existing medical disorders within the Canadian Registry Database (CARESS). **METHODS:** A prospective, observational registry of infants across 29 sites who received at least 1 dose of palivizumab during the 2006-2010 RSV seasons. Neonatal and demographic data were collected from the parent/caregiver at enrollment. Data on palivizumab utilization, compliance, and outcomes related to respiratory illness (RI) events were collected monthly. Premature infants' 35 completed weeks' gestational age (GA) without medical conditions who met standard approval criteria for palivizumab (Group 1) were compared to infants with underlying medical illnesses (Group 2). **RESULTS:** 5832 patients were analyzed (Group 1, n=4880; Group 2, n=952). The two groups were similar in terms of gender (male: 56.4% versus 55.6%; $p=0.829$). Group 2 infants included Down syndrome (n=193, 20.3%), upper airway anomalies (n=178, 18.7%), pulmonary disorders (n=127, 13.3%), cystic fibrosis (n=117, 12.3%), neuromuscular impairment (n=78, 8.2%), multiple system disorders (n=57, 6.0%), cardiac disorders (n=22, 2.3%), immunocompromise (n=17, 1.8%), and miscellaneous (n=163, 17.1%). From 2006-2010, the proportion of Group 2 infants receiving prophylaxis increased 3.4-fold from 5.6% (69/1224) to 19.1% (462/2413). Overall, Group 2 infants were older at enrollment (10.2 ± 9.2 versus 3.5 ± 3.1 months, $p<0.005$), had a significantly higher GA (35.9 ± 6.0 versus 31.0 ± 5.4 completed weeks, $p<0.005$) and had significantly higher RI (9.0% versus 4.2%, $p<0.005$) and RSV hospitalization (2.35% versus 1.32%, $p=0.003$) rates. A lower proportion of Group 2 infants were compliant with treatment (69.4% versus 72.6%, $p=0.048$). There were no serious adverse events directly related to palivizumab.